

## INTEGRATIVE THERAPEUTICS INC."

NF Formulas PhytoPharmica Tyler Encapsulations Vitaline Formulas

ENZYMATIC THERADY

9755 SW Commerce Circle, Suite B2 Wilsonville, OR 97070 P: 503.582.8386 F: 503.582.0467 825 Challenger Drive, Green Bay, WI 54311-8328 P: 920.469.1313 F: 888.570.6460 (Enzymatic)

P: 920.469.9099 F: 920.469.4418 (Phyto)

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July 5, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

JUL 1 1 2005

RE:

Label Claims/Disclaimers

Dear Sir or Madam:

This letter is to notify you that the following product is Manufactured, Packed, and/or Distributed by Enzymatic Therapy, Inc. at 825 Challenger Drive, Green Bay, Wisconsin 54311 has a label that contains a statement provided by section 403(r)(6) of the Federal Food, Drug and Cosmetic Act. Enzymatic Therapy, Inc. wishes to take advantage of the exemption to section 201(g)(1)(C) of the act and comply with section 403(r)(6) of the act. These claims are not necessarily for a product we currently market or plan to market in the immediate future, and may be exploratory in nature.

PRODUCT NAME		INGREDIENT(S)TO WHICH THE CLAIM REFERS
Complete Liver Cleanse*	Complete Liver Cleanse is a special cleansing formula with fiber that goes to work quickly so your liver is thoroughly detoxified!*	Silymarin Phytosome, Dandelion Root Extract, Burdock Root Extract, Boldo (peumus boldo) Leaf Extract, Artichoke Leaf, Turmeric Root DC, Calcium D- glucarate, Choelstatin, Glucomanan, Viscofiber ebta glucan (barley)

I certify that the information contained in this notice is complete and accurate and that Enzymatic Therapy, Inc. has substantiation that the statements are truthful and not misleading.

Robert Doster

Title: Senior Vice President of Scientific Affairs

If you have any questions, please contact Robert Doster, Senior Vice President of Scientific Affairs at (920) 406-3608.

Michael P. Devereux Chief Financial Officer

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PRODUCTINAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Complete Liver Cleanse*	The Complete Liver Cleanse has been scientifically designed to use the right formulation of ingredients to help your body do a better job of supporting liver health.*	Silymarin Phytosome, Dandelion Root Extract, Burdock Root Extract, Boldo (peumus boldo) Leaf Extract, Artichoke Leaf, Turmeric Root DC, Calcium D- glucarate, Choelstatin, Glucomanan, Viscofiber ebta glucan (barley)

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By:

Robert Doster

Title: Senior Vice President of Scientific Affairs

1/5/05

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# ENZYMATIC THERAPY\* & PHYTOPHARMICA\*

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Complete Liver Cleanse*	Once toxins are on the move, you don't want them reabsorbed.*	Silymarin Phytosome, Dandelion Root Extract, Burdock Root Extract, Boldo (peumus boldo) Leaf Extract, Artichoke Leaf, Turmeric Root DC, Calcium D- glucarate, Choelstatin, Glucomanan, Viscofiber ebta glucan (barley)

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KITICIT-

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 7/5/05

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# ENZYMATIC THERAPY

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July 6, 2005

Office of Nutritional Products, Labeling & Dietary Supplements, HFS 810 Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway College Park, MD 20740

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PRODUCTNAME	<u>STATEMENTS</u>	INGREDIENT/S)TOWHICH THE CLAIM REFERS
Complete Liver Cleanse*	For safe and effective cleansing, get the whole family of cleansing products from Enzymatic Therapy.*	Silymarin Phytosome, Dandelion Root Extract, Burdock Root Extract, Boldo (peumus boldo) Leaf Extract, Artichoke Leaf, Turmeric Root DC, Calcium D- glucarate, Choelstatin, Glucomanan, Viscofiber ebta glucan (barley)

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Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/6/05

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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Complete Liver	When bile is moving, Calcium D-	Calcium D-glucarate
Cleanse*	glucarate inhibits the detoxified	
	compounds from reverting back to their	
	original toxic state.*	

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By: \_\_\_\_\_Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 1/6/05

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INTEGRATIVE THERAPEUTICS INC." NF Formulas + PhytoPharmica Tyler Encapsulations \* Vitaline Formulas

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PRODUCTNAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIMIREFERS
Complete Liver Cleanse*	Complete Liver Cleanse has a specially designed fiber that binds to the toxins so they leave the body!*	Silymarin Phytosome, Dandelion Root Extract, Burdock Root Extract, Boldo (peumus boldo) Leaf Extract, Artichoke Leaf, Turmeric Root DC, Calcium D- glucarate, Choelstatin, Glucomanan, Viscofiber ebta glucan (barley)

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Title: Senior Vice President of Scientific Affairs

1/6/05

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# ENZYMATIC THERAPY & PHYTOPHARMICA

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Center for Food Safety and Applied Nutrition Food and Drug Administration 5100 Paint Branch Parkway
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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM/REFERS
Complete Liver	Complete Liver Cleanse has a	Silymarin Phytosome, Dandelion Root
Cleanse*	specially designed fiber that binds to	Extract, Burdock Root Extract, Boldo
	the toxins and removes them from your	(peumus boldo) Leaf Extract, Artichoke
	body.*	Leaf, Turmeric Root DC, Calcium D-
		glucarate, Choelstatin, Glucomanan,
		Viscofiber ebta glucan (barley)

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By: KLICILE

Robert Doster

Title: Senior Vice President of Scientific Affairs

Date: 7/6/05

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P: 503.582.8386 + F: 503.582.0467

PRODUCTNAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Complete Liver	Toxin absorption with fiber*	Silymarin Phytosome, Dandelion Root
Cleanse*		Extract, Burdock Root Extract, Boldo
		(peumus boldo) Leaf Extract, Artichoke
		Leaf, Turmeric Root DC, Calcium D-
		glucarate, Choelstatin, Glucomanan,
		Viscofiber ebta glucan (barley)

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Date: 7/6/05

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Michael P. Devereux Chief Financial Officer ENZYMATIC THERAPY'



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PRODUCT NAME	<u>STATEMENTS</u>	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Complete Liver Cleanse*	Rejuvenate your liver*	Silymarin Phytosome, Dandelion Root Extract, Burdock Root Extract, Boldo (peumus boldo) Leaf Extract, Artichoke Leaf, Turmeric Root DC, Calcium D- glucarate, Choelstatin, Glucomanan, Viscofiber ebta glucan (barley)

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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Complete Liver	Remove toxins and rejuvenate	Silymarin Phytosome, Dandelion Root
Cleanse*	your liver*	Extract, Burdock Root Extract, Boldo
		(peumus boldo) Leaf Extract, Artichoke
		Leaf, Turmeric Root DC, Calcium D-
		glucarate, Choelstatin, Glucomanan,
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PRODUCT NAME	STATEMENTS	INGREDIENT(S)TO WHICH THE CLAIM REFERS
Complete Liver Cleanse*	Milk thistle and other important herbs work together to stimulate the liver and increase bile production.*	Silymarin Phytosome, Dandelion Root Extract, Burdock Root Extract, Boldo (peumus boldo) Leaf Extract, Artichoke Leaf, Turmeric Root DC, Calcium D- glucarate, Choelstatin, Glucomanan, Viscofiber ebta glucan (barley)

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Complete Liver	Beta 1, 3-Glucan, and Konjac flour	Silymarin Phytosome, Dandelion Root
Cleanse*	are fibers that bind with the toxic	Extract, Burdock Root Extract, Boldo
	excretions to prevent reabsorption	(peumus boldo) Leaf Extract, Artichoke
	back into the body. These fibers	Leaf, Turmeric Root DC, Calcium D-
	move the toxins out so they are	glucarate, Choelstatin, Glucomanan,
	eliminated.*	Viscofiber ebta glucan (barley)

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Michael P. Devereux

Chief Financial Officer